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| 10/591,095 | 09/20/2006 | Valerie Frankard | 14546-00001-US | 4358 |
| 23416 7590 04/15/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,095

Applicant(s)

FRANKARD, VALERIE

Examiner

Cynthia Collins

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 21, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 13, 15-18, 20, 21, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed January 21, 2009 has been entered.

Claims 14 and 19 are cancelled.

Claims 1, 4, 5, 8, 12, 13, 16 and 21 are currently amended.

Claims 10-11 and 22 are withdrawn.

Claims 1-13, 15-18 and 20-24 are pending.

Claims 1-9, 12-13, 15-18, 20-21 and 23-24 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

It is noted that the proper status of claim 22 is withdrawn, as claim 22 depends from withdrawn claim 10.

Claim Objections

Claims 4, 5, 8, 13, 16 and 21 are objected to because of the following informalities: the claims do not comply with 37 CFR 1.182, which requires that reference be made to a sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the claims, even if the sequence is also embedded in the text of the claims of the patent application. The sequence at issue is "NXTALRE", added by amendment. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 requires the presence of at least a GOS2 promoter.

The specification describes a single promoter having the sequence of SEQ ID NO:3 obtained from rice that has the designation "GOS2". (Figure 3). The specification does not describe other sequences having the designation "GOS2" that function as a "GOS2" promoter.

The Federal Circuit has clarified the application of the written description requirement to nucleic acids. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for

Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106, where it is set forth that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002).

In the instant case Applicant has not described a representative number of species falling within the scope of the genus required by the rejected claim, which genus encompasses promoter sequences of unspecified structure having the designation "GOS2", nor the structural features unique to the genus that are correlated with the functional attributes of a "GOS2" promoter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fabian-Marwedel T. et al. (The rice cyclin-dependent kinase-activating kinase R2 regulates S phase

progression. *Plant Cell*. 2002 Jan;14(1):197-210) in view of de Pater B.S. et al. (The promoter of the rice gene GOS2 is active in various different monocot tissues and binds rice nuclear factor ASF-1. *Plant J*. 1992 Nov;2(6):837-44).

The claim is drawn to a construct comprising: a CDKD-encoding nucleic acid or a nucleic acid which encodes a CDKD comprising an NXTALRE motif and a catalytic kinase domain (ii) one or more control sequence capable of driving expression of the nucleic acid sequence of including a constitutive promoter (i) which comprises at least a GOS2 promoter; and optionally (iii) a transcription termination sequence.

Fabian-Marwedel T. et al. a construct comprising (i) a rice plant CDK-activating kinase R2 encoding nucleic acid; (ii) a maize ubiquitin promoter; and (iii) a nopaline synthase terminator sequence (page 207 column 2). The rice plant CDK-activating kinase R2 encoding nucleic acid is a CDKD-encoding nucleic acid (Joubes J. et al. CDK-related protein kinases in plants. *Plant Mol Biol*. 2000 Aug;43(5-6):607-20. Review. See page 612 Table 1), and encodes a CDKD comprising an NXTALRE motif and a catalytic kinase domain (Genbank ACCESSION NO. P29620, November 25, 2008). Fabian-Marwedel T. et al. also teach rice plant cells transformed with a construct comprising (i) a rice plant CDK-activating kinase R2 encoding nucleic acid; (ii) a maize ubiquitin promoter; and (iii) a nopaline synthase terminator sequence (page 201 Figure 3; page 202 Figure 4). Fabian-Marwedel T. et al. additionally teach that increasing R2 abundance through a transgenic approach accelerates S-phase progression and overall growth rate in suspension cells (abstract; page 202 Figure 4; page 203 Figures 5 and 6).

Fabian-Marwedel T. et al. do not teach a GOS2 promoter.

de Pater B.S. et al. teach a GOS2 promoter obtained from rice that drives the expression of a gusA reporter gene in a variety of rice tissues and in cell suspensions of other monocot species following introduction by particle bombardment (page 840 Figure 6; page 841 Figure 7).

Given the teachings of Fabian-Marwedel T. et al. that rice plant cells transformed with a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter have an accelerated S-phase progression and overall growth rate, and given the teachings of de Pater B.S. et al. that a GOS2 promoter obtained from rice drives the expression of an operably linked gene in a variety of rice tissues and in cell suspensions of other monocot species following introduction by particle bombardment, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to substitute the GOS2 promoter taught by de Pater B.S. et al. for the ubiquitin promoter in the construct taught by Fabian-Marwedel T. et al. One skilled in the art would have been motivated to do so in order to express a rice plant CDK-activating kinase R2 encoding nucleic acid in rice plant cells. One skilled in the art would have had a reasonable expectation of success given the success of Fabian-Marwedel T. et al. in overexpressing a rice plant CDK-activating kinase R2 encoding nucleic acid in rice plant cells using a ubiquitin promoter and given the success of de Pater B.S. et al. in expressing a reporter gene in a variety of rice tissues and in cell suspensions of other monocot species using the GOS2 promoter. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Claims 1-9, 12, 15, 18, 20-21 and 23-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fabian-Marwedel T. et al. (The rice cyclin-dependent kinase-activating kinase R2 regulates S phase progression. *Plant Cell*. 2002 Jan;14(1):197-210) in view of Komari T. et al. (Advances in cereal gene transfer. *Curr Opin Plant Biol*. 1998 Apr;1(2):161-5. Review), for the reasons of record set forth in the office action mailed August 19, 2008.

Applicant's arguments filed January 21, 2009 have been fully considered but they are not persuasive.

Applicants disagree with the Examiner's position that the preamble recites an intended use, and Applicants note that the claims have been amended without disclaimer or prejudice and relate to a method which results in a transgenic plant having increased plant yield relative to a corresponding wild type plant and to a construct comprising a CDKD-encoding nucleic acid and a control sequence which comprises a GOS2 promoter. Applicants maintain that because neither Fabian-Marwedel nor Komari teach a transgenic plant having increased yield or increasing plant yield relative to a corresponding wild type plant nor the claimed construct, Fabian-Marwedel and Komari, alone or in combination, do not disclose or suggest all the limitations of the claimed invention.

Applicants' arguments are unpersuasive, as the increased yield recited in the claims as amended is the end result of practicing the claimed method, and is thus inherent to method. The Examiner also maintains that none of the rejected claims (claims 1-9, 12, 15, 18, 20-21 and 23-24) require a GOS2 promoter.

Applicants also disagree with the Examiner's position that that the nucleic acid taught by Fabian-Marwedel is capable of hybridizing to the sequence of SEQ ID NO: 1, as the identity based on the full-length sequence of SEQ ID NO: 1 would be much less than 39.8% identity, and the Examiner has not established that hybridization under the conditions set forth in the claims and the specification could occur with such a low percent identity over only a portion of the SEQ ID NO: 1.

Applicants' arguments are unpersuasive, as hybridization conditions set forth in the specification do not limit the claims, and as no specific hybridization conditions are set forth in the rejected claims.

Applicants additionally note that the teachings of Fabian-Marwedel relate to an effect observed in suspension cells, and that there is no indication in either Fabian-Marwedel or Komari that this effect could be reproduced in whole plants. Applicants maintain that even if an increase in growth rate were observed, there is no indication whether this growth rate, *i.e.* increased speed of growth, would translate into an increase in plant yield, and that the record does not provide any evidence that there would be an expectation of success that the method would result in transgenic plants having increased yield relative to a corresponding wild-type plant as required.

The Examiner maintains that neither Fabian-Marwedel nor Komari need explicitly teach that an effect observed in suspension cells could be reproduced in whole plants in order to render the claimed invention obvious, since one skilled in the art would be apprised that

whole plants comprise cells, including dividing cells as are characteristic of cells in suspension. Applicants' arguments also are unpersuasive, as the increased yield recited in the claims as amended is the end result of practicing the claimed method, and is thus inherent to method.

Applicants also point out that Cornejo et al. cited by the Examiner in the rejection of claims 16-17 and 24, characterizes the expression of the ubiquitin promoter in transgenic calli and plants, and teaches that seed set in the transgenic R0 plants was reduced compared to untransformed plants. Applicants maintain that one of ordinary skill in the art would thus not have a reasonable expectation of success of obtaining plants with increased yield based on the teaching of Fabian-Marwedel of a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter, where Cornejo teaches that use of the same promoter resulted a decreased seed yield in transgenic plants.

Applicants' reliance on Cornejo et al. is misplaced as Cornejo et al. was not applied to claims 1-9, 12, 15, 18, 20-21 and 23-24. Applicants' reliance on Cornejo et al. is also misplaced as it is the type of transgene expressed from the promoter that would affect seed set, and Cornejo et al. expressed a different type of transgene (GUS and BAR) than expressed in the claimed method (CDKD).

Claims 16-17 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fabian-Marwedel T. et al. (The rice cyclin-dependent kinase-activating kinase R2 regulates S phase progression. Plant Cell. 2002 Jan;14(1):197-210) in view of Komari T et al.

(Advances in cereal gene transfer. Curr Opin Plant Biol. 1998 Apr;1(2):161-5. Review) and Cornejo M. et al. (Activity of a maize ubiquitin promoter in transgenic rice. Plant Mol Biol. 1993 Nov;23(3):567-81), for the reasons of record set forth in the office action mailed August 19, 2008.

Applicant's arguments filed January 21, 2009 have been fully considered but they are not persuasive.

Applicants maintain that the explanations provided above for Fabian-Marwedel and Komari are equally applicable to this rejection and are incorporated herein in their entirety.

The Examiner maintains that Applicants' arguments with respect to Fabian-Marwedel and Komari are unpersuasive, for the reasons set forth above.

Applicants also reiterate that Cornejo et al. teaches that seed set in the transgenic R0 plants was reduced compared to untransformed plants, and maintain that one of ordinary skill in the art would thus not have a reasonable expectation of success of obtaining plants with increased yield based on the teaching of Fabian-Marwedel of a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter, where Cornejo teaches that use of the same promoter resulted a decreased seed yield in transgenic plants.

The Examiner maintains that Applicants' arguments are unpersuasive as it is the type of transgene expressed from the promoter that would affect seed set, and Cornejo et al. expressed a different type of transgene (GUS and BAR) than expressed in the claimed method (CDKD).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC